DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 25, 2016

Omm Imports Inc Dba Zero Gravity
% Ms. Susan Anthoney-DeWet
Aegis Regulatory, Inc.
2424 Dempster Drive
Coralville, IA 52241

Re: K152332
Trade/Device Name: Perfectio LED Infrared Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: OHS
Dated: January 27, 2015
Received: January 27, 2015

Dear Ms. Anthoney-DeWet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Post-market Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152332

Device Name
Perfectio LED infrared Device

Indications for Use *(Describe)*
Perfectio LED infrared device is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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OMM IMPORTS INC DBA ZERO GRAVITY;
1945 S OCEAN DR APT 509 HALLANDLE BEACH BLVD,FLORIDA 33009

Section 5
510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K152332
Date:	Aug 10, 2015
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	OMM IMPORTS INC DBA ZERO GRAVITY; 1945 S OCEAN DR APT 509 HALLANDLE BEACH BLVD,FLORIDA 33009, US
Contact:	Doris Dong (Consultant) Shanghai CV Technology Co., Ltd. Room 1706, No. 128 Songle Rd., Songjiang Area, Shanghai, 201600 China E-mail: doris_d@126.com Tel: 86 21-31261348

2. Device Description:

Proprietary Name:	Perfectio LED infrared device
Common Name:	Light Emitting Diode (LED) device
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code:	OHS
Device Class:	II
Regulation Number:	21 CFR 878.4810
Review Panel:	General & Plastic Surgery
Indications for use:	Perfectio LED infrared device is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.
Device Description:	Perfectio LED infrared device is a battery operated device that uses low power light spectrum at red and infrared LED, at wavelength of 633 ±5nm, 830 ±5nm emitting optical power in a uniform distribution with no hot spots. The device is composed of a handpiece for delivery of light energy, base unit for charging and storage when not in use, and A.C. charging adapter. It is a hand held light emitting diode (LED) device for the treatment of periorbital wrinkles designed for home-use.

3. Predicate Device Identification

510(k) Number: K110301
Clearing date: August 19, 2011
Product Name: Silk'n FX
Manufacturer: Home Skinovations Ltd.

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4. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device conforms with the following standards:

* AAMI / ANSI ES60601-1:2005/(R) 2012 And A1:2012, C1:2009/(R) 2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.
* IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests.
* IEC 60601-1-11:2010, Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
* IEC 62471:2006, Photobiological Safety of Lamps and Lamp Systems

The patient contact materials in Perfectio LED infrared device are the body housing material of ABS and the head housing material of Stainless steel 304. Both the two materials were tested and found to meet the biocompatibility standards of:

* ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
* ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity, and
* ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

A Usability/Label Comprehension Study was conducted with 35 participants.
The results of the study showed that (100%) were able to:
-Correctly self-select as being an appropriate user of the device.
-Correctly demonstrate how to set up the device, perform the Light Sensitivity Test, operate the device (apply Tx), and clean the device.
And that (95%) of participants were able to correctly answer each question for the Questionnaire portion of the Study.

5. Substantial Equivalent Based on Assessment of Clinical Performance Data:

Clinical data was not included in this submission.

6. Substantially Equivalent Comparison Conclusion

	New Device	**Predicate Device**
510(k) Number:	K152332	K110301
Product Code:	OHS	OHS
Proprietary Name:	Perfectio LED infrared device	Silk’n FX
Manufacturer:	OMM IMPORTS INC DBA ZERO GRAVITY	Home Skinovations Ltd.
Indications for use:	Perfectio LED infrared device is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of	Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of

	periorbital wrinkles.	periorbital wrinkles.
Handheld	Yes	Yes
Materials	ABS and stainless steel	ABS and stainless steel
Wavelengths	633 ±5nm, 830 ±5nm	633 ±5nm, 830 ±5nm
Light source	Light emitting diode(LED)	Light emitting diode(LED)
Waveform	Constant	Constant
Energy Source	25 LEDs over 17cm^2	24 LEDs over 12 cm^2
Power supply	Adaptor:100~240V AC 50/60Hz 0.2A Lithium battery: 2x3.7V, 900 mAh	Adaptor:100~240V AC 50/60Hz 0.4A Lithium battery: 2x3.7V, 750±50mAh
Initial treatment course	For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each time.(5-7 minutes on each treatment zone).	For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each time.(5-7 minutes on each treatment zone).
Maintenance regime	Once a week for 15-20 minutes	Once a week for 15-20 minutes
Target Population	Individuals with periorbital lines and wrinkles	Individuals with periorbital lines and wrinkles
Location for use	OTC	OTC
Standard meet	IEC60601-1 IEC60601-1-2 IEC60601-1-11 IEC62471	IEC60601-1 IEC60601-1-2 IEC62471

The Conclusions:

Taking into consideration the table for substantial equivalence, an analysis of safety, indications, intended uses, performance, and technological properties, the proposed device raises no new issues of safety or effectiveness and has been found to be substantially equivalent to the predicate device.